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EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,149

Applicant(s)

SAVOIE ET AL.

Examiner

Robert M. Kelly

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,6,7 and 10-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6,7 and 10-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/2/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election of 11/10/05 is entered.

Claims 1-40 are presently pending.

Election/Restrictions

Applicant's election of Group I, Claims 1-10 and the further election of FAR1 within that group in the reply filed on 11/10/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-3, 6-7, 10, and 11-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/10/05.

Claims 1, 5-6, and 8-9 are presently considered.

Note: Re Applicant's Election

Applicant's election states that they "expressly reserve the right to prosecute other non-elected claims at a later stage" (Applicant's response of 11/10/05, p. 1). However, the Examiner asserts that Applicant is not due any right to prosecute other non-elected claims. Each of Applicant's elections was due to each invention being separate, independent, and patentably distinct. Moreover, with regard to the species election, species election practice was expressly demonstrated to not exist for Applicant's species (Restriction requirement of 6/29/05, p. 5, paragraphs 1-3). The Examiner clearly called such target genes species because Applicant wrote

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the claims in the form of species, not because they are linked as species within a genera. Clearly, the election of species was a Group Restriction (Restriction requirement of 6/29/05, p. 5, paragraph 1), in which each of the target genes are patentably distinct, with distinct structure and function, which would require distinct structural and functional considerations (Id., paragraphs 2-3). Hence, the Examiner is not bound to follow species election practice under 35 USC 121, and instead a Restriction requirement within the initially-elected invention was required (Id., pp. 1-2).

To put it another way, even though Applicant wrote the claims as a set of species, and therefore the Examiner has referred to the target genes as species, the form paragraph for species elections under 35 USC 121 was not followed, as indicated by the requirement for restriction (Id., p. 5, paragraph 1). Simply put, these are not true species as in the spirit of such species elections under 35 USC 121, as they have and require completely distinct structure and functions (e.g., Id., p. 5, paragraph 3). Therefore, Applicant will not be due consideration of any non-elected claims at a later time in the prosecution of this Application.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

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The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

It is noted that Applicant's abstract does not reflect the claimed invention, nor does it even mention the elected invention.

Information Disclosure Statement

The references listed in Applicant's information disclosure statement of 11/2/04 have been considered, but the reference to the international search report has been crossed out, because such is not a publication and could not, therefore, be listed on the face of any patent that may issue from this Application.

Claim Objections

Claims 1, 4-5, and 8-9 are objected to for encompassing non-elected inventions.

Applicant is required to amend the claims to exclude non-elected inventions.

Claim Rejections - 35 USC § 112 - indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 recites the limitation “wherein the agent affects a target gene whereby affecting the antifungal activity in the system”. The metes and bounds of such limitation are not clear. It is suggested that Applicant amend the claim to recite “wherein the agent affects a target gene, thereby affecting the antifungal activity in the system”.

Claim 4 recites the limitation “wherein the agent inhibits the activity of CIK1 and whereby the antifungal activity in the system is increased”. It is unclear whether Applicant that the agent also inhibits the activity of CIK1 or simply inhibits CIK1. Therefore, the claim has been considered with respect to “also inhibiting the activity of CIK1”, for purposes of compact prosecution. (It is noted that if it only affects CIK1, then the claim is a non-elected invention.)

Claim 8 recites the limitation “the agent affects a target gene involved in the CIK1 pathway whereby decreasing the activity of CIK1”. The metes and bounds of such limitation are not clear. It is suggested that Applicant amend the claim to recite “the agent affects a target gene involved in the CIK1 pathway, thereby decreasing the activity of CIK1”

Claim 8 is also rejected for rejected for not providing a complete method, i.e., the method does not result in increasing the antifungal activity of the system. Hence, the method is incomplete and leads the Artisan to not understand how to accomplish the method.

Claims 4-5 and 9 are rejected for depending from a rejected base claim, and not further overcoming the lack of clarity in such base claim.

Claim Rejections - 35 USC § 112 – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's claims encompass the following generic limitations:

- (i) affecting the antifungal activity in a generic system;
- (ii) a generic FAR1 gene;
- (ii) a generic agent that affects a generic FAR1 gene;
- (iii) a generic agent that affects a generic FAR1 gene and affects a generic CIK1 gene, thereby increasing antifungal activity of a system;
- (iv) increasing the antifungal activity of any system; and
- (v) a generic agent that affects FAR1, thereby decreasing the activity of a generic CIK1.

These generic limitations are not supported by the specification and art such that the Artisan could reasonably determine that Applicant held possession of the various generic limitations at the time of filing.

Applicant's specification teaches that various genes and any gene in the pathways involved in those genes can be used for identifying antifungal agents (p. 4). Such genes include

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the receptor FAR1, which is associated with CIK1 (p. 5). Moreover, the target gene can be found in any organism, including microorganisms, for example, fungi (p. 5). The target genes can be used in parallel analysis of each target gene, which may be in crystalline form, and used in high-throughput analyses, through some undetermined method (p. 6). Drugs may also be found by determining the crystalline structure of the protein encoded by the target genes (p. 7). Further, screening assays for inhibitors or enhancers of the genes are also provided (p. 8). Also, any screen demonstrating any change in any activity of the target gene or any activity of the encoded protein is encompassed (p. 8). Still also, the antifungal activity or a fungal infection response in any system, e.g., a human, can be performed to identify such agents. Lastly, for all of these genes, any agent can be administered to any system in order affect any expression or activity of the target gene or its expressed protein, or any protein in any pathway in which the target gene's protein is involved, in order to affect, in any way, any antifungal activity of the generic system (e.g., pp. 10-11). It is further noted that Applicant has not provided even one single agent in their specification.

The Art teaches that FAR1 is a bifunctional protein required to arrest the cell cycle and establish cell polarity during yeast mating (Blondel, et al. (2000) EMBO J., 19(22): 6085-97).

However, given the generic claiming of any FAR1 gene from any organism, and the fact that the Art only recognizes that FAR1 is found in yeast, the Artisan could not determine that Applicant had possession of any generic FAR1 from any species.

With regard to affecting or increasing any antifungal activity in any system, Applicant has only shown that they intend to affect antifungal activity with regard to yeast, as yeast are the only organism known to possess FAR1.

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With regard to any system, Applicant has not demonstrated possession of any system other than yeast systems, as, for example, bacteria do not possess FAR1.

With regard to agents that affect any particular activity, Applicant has not discussed any such agent, and therefore, the Artisan could not determine Applicant had possession of the species encompassed. Moreover, while Applicant proposes various generically described screens, such screens does not demonstrate possession of those agents that have the required activities.

With regard to an agent that affects both FAR1 and CIK1, Applicant has provided no such agent, and while various generic screens are generically described, such screens do not demonstrate possession. Hence, the Artisan could not reasonably determine had possession of the generic agents.

Claim Rejections - 35 USC § 112 - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue

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experimentation” to make and/or use the invention claimed. Such a determination is not a simple factual consideration, but is a conclusion reached by weighing at least eight factors as set forth in In re Wands, 858 F.2d at 737, 8 USPQ.2d at 1404. Such factors are:

- (1) The breadth of the claims;
- (2) The nature of the invention;
- (3) The state of the art;
- (4) The level of one of ordinary skill in the art;
- (5) The level of predictability in the art;
- (6) The amount of direction and guidance provided by Applicant;
- (7) The existence of working examples; and
- (8) The quantity of experimentation needed to make and/or use the invention.

These factors will be analyzed, in turn, to demonstrate that one of ordinary skill in the art at the time of invention (hereinafter the “Artisan”) would have had to perform “undue experimentation” to make and/or use the invention, and that, therefore, Applicant’s claims are not enabled.

The Breadth of the Claims

Claims 1 and 4-5 encompass a method of affecting an antifungal activity in any system comprising the administration, by any route, of any agent, wherein the agent affects the FAR1 target gene, thereby affecting any antifungal activity in the system. Claim 4 limits the agent to also inhibiting any activity of CIK1, thereby increasing any antifungal activity in the system. Claim 4 limits the agent to FAR1.

Claims 8-9 encompass a method of increasing the (i.e., the only) antifungal activity in a system, comprising administering any agent, by any route, which the agent affects the FAR1 gene, which is involved in the CIK1 pathway, thereby decreasing the activity of CIK1. Claim 9 limits agent to affecting the gene of FAR1.

Moreover, it is clear from Applicant's specification, that affecting the FAR1 target gene actually encompasses the FAR1 gene itself, the mRNA transcribed, the protein translated, or any gene or protein associated with any pathway that FAR1 is involved with (e.g., SPECIFICATION, p. 8). Hence, Applicant's agents are much broader than they might appear *a priori*.

Applicant's claims are broad for encompassing any system, any antifungal activity, any agent that affects the FAR1 target gene, and any agent that affects both the FAR1 target gene and inhibits an activity of CIK1. As such, the Artisan would require quite a bit of information to reasonably predict the working embodiments encompassed by the methods.

The Nature of the Invention and State of the Prior Art

Applicant's claimed invention is in the nature of treating fungal infections in any system, by the administration, by any route, of any agent that affects the FAR1 target gene, and optionally further inhibits an activity of CIK1.

The agents, being, optionally, small compounds like typical antifungals, such as griseofulvin (Goodman and Gilman's, The Pharmacological Basis of Therapeutics, 1980, MacMillan Publishing, New York, NY, p. 1237), larger compounds, nucleic acids, and anything else under the sun, as long as they affect any gene or protein related in any way to FAR1, or FAR1 itself, suffer from many problems with regard to delivery in any particular system. To

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wit, while administration of the compound to yeast in an isolated Petri dish may be reasonably predicted to obtain antifungal effects, administration of such compounds to an organism is exceedingly difficult, suffering from many problems with regard to the various barriers involved, and which barriers are further compounded in the case of gene therapy type techniques.

With regard to gene therapy, while progress has been made in recent years for gene transfer *in vivo*, vector targeting to desired tissues *in vivo* continues to be a difficulty as supported by numerous teachings available in the art. For example, Deonarain (1998) Expert Opin. Ther. Pat., 8: 53-69, indicates that one of the biggest problems hampering successful gene therapy is the “ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time” (p. 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (p. 65, CONCLUSION). Verma (1997) Nature, 389: 239-242, reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (p. 240, sentence bridging columns 2 and 3). Verma states that “The Achilles heel of gene therapy is gene delivery and this is the aspect we will concentrate on here. Thus far, the problem has been an inability to deliver genes efficiently and to obtain sustained expression ... The use of viruses (viral vectors) is a powerful technique, because many of them have evolved a specific machinery to deliver DNA to cells. However, humans have an

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immune system to fight off the virus, and our attempts to deliver genes in viral vectors have been confronted by these host responses (e.g., p. 239, col. 3).

Further, Eck et al. (1996) Goodman & Gilman's The Pharmacological Basis of Therapeutics, McGraw-Hill, New York, NY., pp. 77-101, states that the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, and the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced, are all important factors for a successful gene therapy (e.g., bridging pp. 81-82). In addition, Gorecki (2001) Expert Opin. Emerging Drugs 6(2): 187-98) reports that "the choice of vectors and delivery routes depends on the nature of the target cells and the required levels and stability of expression" for gene therapy, and obstacles to gene therapy *in vivo* include "the development of effective clinical products" and "the low levels and stability of expression and immune responses to vectors and/or gene products" (e.g., ABSTRACT).

Such is also not limited to limited to gene therapy, as shown by Langer (2003) Scientific American, 288(4): 50-57, which delineates a number of difficulties in delivering compounds, including resisting the compound's degradation by acids and enzymes, crossing the various tissue barriers, including the blood brain barrier, clearance by the kidneys and liver and crossing the blood-brain barrier. Hence, the Artisan would not be able to predict that such methods would even work *in vivo*, because the Artisan would not be able to predict that enough of each

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component would reach each of the cells in which the experiment was to take place.

Further, any specific antifungal agent may actually kill the patient before any antifungal treatment actually takes place, and if not, may require very specific dosing in order not to kill such patient before therapeutic effects are had. To wit, Dumaine, et al. (1998) J. Pharmacol. Exp. Therap., 286(2) : 727-735, discloses an antifungal agent that is widely used in patients that can block unforeseen genes, including the HERG gene, and thereby cause cardiac problems that may kill the patient, and therefore is recommended to have very strict dosing schedules (ABSTRACT). Hence, the Artisan would not be able to reasonably predict that any other agent so-administered by any particular route would not have other unforeseen effects such that it might kill the patient before antifungal therapy is found.

Lastly, the Artisan would not know what compounds may be used to affect these genes and their proteins, and as such, could not reasonably predict which compounds may be used in the methods.

The Level of One of Ordinary Skill in the Art at the Time of Invention

The level of one of ordinary skill in the art at the time of invention was advanced, being that of a person holding a Ph.D. or an M.D.; however, because of the immaturity of the art, and its unpredictability, as shown by the other factors, one of skill in the art at the time of invention by Applicant would not have been able to make and/or use the invention claimed without undue experimentation.

The Level of Predictability in the Art

Because of the art, as shown above, does not disclose enough to reasonably predict the compounds useful in the methods, the methods of administration, and whether any specific

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compound may kill any particular patient, the Artisan could not predict, in the absence of proof to the contrary, that such applications would efficacious in any therapeutic treatment.

Hence, absent a strong showing by Applicant, in the way of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by Applicant is not enabled.

The Amount of Direction and Guidance Provided by Applicant

Applicant's specification broadly discusses fungal infections and the need to treat them (p. 1), broad description roughly tracking claim language (pp. 1-4), target genes, and subsequences (pp. 4-5), target genes may be found in any organism (p. 5), polypeptides encoded by the target genes (pp. 5-6), databases comprising listings of the target genes and relationship identifiers (p. 6), parallel analysis of such target genes through high-throughput analysis (p. 6), crystalline forms of the target genes, and their use to identify agents that affect the target genes (p. 7), screening assays for target genes and their expression/activity (pp. 7-8), and broad language stating that affecting the various target genes can be affected, or other genes related in any pathway to the target gene, to thereby affect antifungal activity (pp. 9-10), and, lastly, broad description of formulations and administrations.

However, such does not constitute the specific direction and guidance the Artisan would require to overcome the various bases lacking reasonable predictability listed in the nature of the invention and state of the prior art. Hence, Applicant's specification does nothing to overcome these bases.

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The Existence of Working Examples

Applicant has provided no working examples. Hence, Applicant's specification is no more enabling than the prior art.

The Amount of Experimentation Required to Practice the Claimed Invention

The Artisan would be required to determine which molecules may be applied to which systems, in order to target which FAR1 genes, or genes associated therewith, to affect FAR1 expression/activity, and further CIP1 activity, to provide an antifungal effect. Moreover, the Artisan would have to experiment to determine if any particular route of administration would be efficacious, if any particular agent would actually kill the patient before therapy could take place, and which antifungal activities could be effected.

Such experimentation is undue, amounting to effectively inventing Applicant's claimed subject matter for Applicant.

Conclusion

Because of the finding of undue experimentation, Applicant's claims are not enabled.

Art Rejections

Due to the Breadth of Applicant's claims, encompassing direct or any indirect effect on FAR1 target genes, no matter how indirect such influence is, the following rejection is held even in light of the lack of enablement above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Goodman and Guilman's, "The Pharmacological Basis of Therapeutics," MacMillan Publishing Co., 6th Ed., pp. 1237-38 (1980).

The cited reference teaches griseofulvin (pp. 1237-38), which is an antifungal agent. Dosing and preparations are provided for administration to subjects (p. 1238).

Hence, the reference teaches an agent which will certainly kill fungal cells, as it is used for such treatment, and necessarily would decrease expression of both FAR1 and CIK1, whether directly or indirectly.

Conclusion

No Claim is allowed.

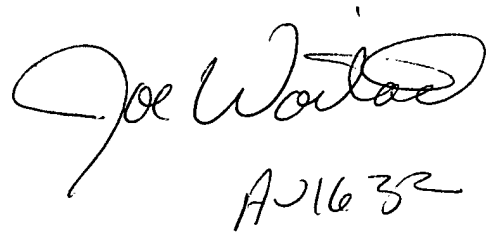
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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